K083016

FEB - 9 2009

SPECIAL 510(K) SUMMARY (21 CFR 807.92)

HYDROMARK BREAST BIOPSY SITE MARKER

510(k) Owner: Biopsy Sciences, LLC.
3433 East Fort Lowell Road, Suite 103
Tucson, AZ 85716
Tel: 520-325-9086
Fax: 520-881-4686

Contact Person: Sharon Rockwell
Tel: 714-695-9269
E-mail: srockwell@writeme.com

Date Prepared: October, 2008

Trade Name: HydroMark Breast Biopsy Site Marker

Common Name: Biopsy site marker

Classification: Implantable stable per 21 CFR section 878.4750, FZP

Predicate Devices: Biopsy Sciences HydroMark Breast Biopsy Site Marker, K060769

Device Description: The Biopsy Sciences HydroMark Breast Biospy Site Markers are made of resorbable FocalSeal-L Surgical Sealant, the same material used in the Biopsy Sciences Lung Biopsy Site Marker and in the currently cleared HydroMark Breast Biopsy Site Marker. The HydroMark is visible under mammography, ultrasound and magnetic resonance imaging. It expands in the void created during biopsy and does not migrate. The FocalSeal-L hydrogel material degrades in a manner similar to absorbable sutures, via hydrolysis. The HydroMark is available with either stainless steel or titanium coils, depending on physician preference. Both coils provide permanent visibility under x-ray and MRI.

The HydroMark Site Marker is provided pre-loaded in a sterile, disposable applicator that is compatible with the J&J Ethicon Endo-Surgery Mammotome probe. The HydroMark is deployed by the delivery system through the Mammotome probe and is left in the void created during the biopsy procedure.

Intended Use: The Biopsy Sciences, LLC. HydroMark Biopsy Site Marker is intended to mark tissue during a percutaneous breast biopsy

procedure, be visible under ultrasound for at least 6 weeks, and be permanently visible by x-ray and MRI.

The indications are identical to those of the predicate device, the Biopsy Sciences HydroMark Breast Biopsy Site Marker.

Substantial Equivalence:

The modified HydroMark Breast Biopsy Site Marker has the same indications for use as the predicate site marker. The modification to the device includes offering the option of a either a stainless steel coil or a titanium coil, both of which are permanently visible under x-ray and MRI. Any differences between the modified device and the original HydroMark do not raise new questions of safety or effectiveness.

Technological Characteristics:

The HydroMark is a two component device. The outer hydrogel component expands on fluid contact to fill the void created during the biopsy, leaving the device at the exact location of biopsy. Because the hydrogel is hydrophilic, it is clearly distinct from normal breast structure under ultrasound imaging. The hydrogel material degrades via hydrolysis over time leaving the internal stainless steel or titanium coil to provide permanent visibility under x-ray and MRI.

Non-Clinical Performance Data:

Non-clinical testing includes comparing the MRI images of the stainless steel coil to the predicate titanium coil. Both coils are readily visible under MRI with minimal artifacts.

Conclusions:

Biopsy Sciences has determined, based on comparative studies, that the stainless steel coil is as safe and effective as the predicate titanium coil, and that the device conforms to the original design specifications. The modified device is substantially equivalent to the predicate.

Any statement regarding "substantial equivalence" made in this 510(k) submission and summary only relates to whether the product addressed in this submission may be lawfully marketed without premarket approval or reclassification, and is not intended to be interpreted as an admission or any other type of evidence in any *patent proceeding, including patent infringement, litigation or proceeding before any Patent Office. The present submission and statements therein therefore should not be construed as affecting or relating to the scope of any patent or patent application, or to whether the product addressed in this submission, or its use, may be considered indistinct, from a patentability perspective, from any of the other devices referenced in this filing.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 9 2009

Biopsy Sciences, LLC
% Ms. Sharon Rockwell
Director of Regulatory Affairs
Biopsy Sciences, Inc.
5582 Chalon Road
YORBA LINDA CA 92886

Re: K083006
Trade/Device Name: Biopsy Sciences HydroMark Breast Biopsy Site Marker
Regulation Number: 21 CFR 878.4750
Regulation Name: Implant staple
Regulatory Class: II
Product Code: NEU
Dated: December 18, 2008
Received: December 22, 2008

Dear Ms. Rockwell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K083006

Device Name: Biopsy Sciences HydroMark Breast Biopsy Site Marker

Indications for Use:

The Biopsy Sciences LLC., HydroMark Biopsy Site Marker is intended to mark tissue during a percutaneous breast biopsy procedure, be visible under ultrasound for at least 6 weeks, and be permanently visible by x-ray and MRI.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K083006